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EXAMINER	
LARYEA, LAWRENCE N	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
06/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/516,297	Applicant(s) SCHMIDT ET AL.	
	Examiner LAWRENCE N. LARYEA	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on no date is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/09/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). **The drawings must show every feature of the invention specified in the claims.** Therefore, the “an operating microscope, at least one optoelectronic image receiver, a microscope, and a computer system, and the data obtained from the at least one image receiver, each of which lie in the microscope field-of-view of the operator, contain information about the location of the operating instrument, especially of the tip of this instrument, wherein the actual position of the instrument in the x- and y-direction as well as in the z-direction of a three-dimensional coordinate system is continuously or intermittently determined from the respective location data and wherein especially for the positional determination in the z-direction a distance determination is carried out by means of a depth of focus evaluation and/or or a stereoscopic image analysis and/or an evaluation of the signals obtained by a PMD sensor (Photonic Mixer Device) including the pertinent modulated illumination. ” in Claim 1, and most “imaging system having at least two different adjustable magnification” and **every feature of the invention specified in the all claims** must be shown or the feature(s) canceled from the claim(s). ***No new matter should be entered.***

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

Art Unit: 3768

number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

4. Claims 1-35 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 1, 2, 12, 18, 21, 26-30 the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1 recites the limitation "the operator" at line 7.

Claim 1 recites the limitation "the location of the operating instrument" at lines 7-

8.

Claim 1 recites the limitation "the respective location data" at lines 10-11.

Claim 1, line 12, after and/or "or" should be deleted.

Claim 1 recites the limitation "the pertinent modulated illumination" at line 14.

Claim 2 recites the limitation "the observation beam path" at lines 3-4.

Claim 3 recites the limitation "the observation beam path" at lines 3-4.

Claim 4, line recite the limitations "the current position of the patient" at line 7.

There are insufficient antecedent basis for these limitations in the claims.

7. The term "higher" in claim 4, line 6 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide

Art Unit: 3768

a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 6, line 3, it is unclear what happens if the valid data records does not exist in only one of said two systems respect to phrase “if ”

Claim 7, line 3, it is unclear what happens if the redundant data records does not defined exit as being valid exit with respect to phrase “if”

Claim 7, line 3 recites the limitation “the same ”.

Claim 7, line 4 recites the limitation “ the measuring exactness and/or to quantify the measuring exactness.”

Claim 9, line 4 recites the limitation “ the tissue surface of the patient”, the brain shifting at the open skull”.

Claim 10, line 5 recites the limitation “the same magnification.”

Claim 10, line 6 recites the limitation “the distortion errors ”.

Claim 10, line 6-7 recites the limitation “ the stereoscopic image analysis” and “the currently used settings of zoom and focus.”

Claim 11 recites the limitations “the parameters of the mentioned correction function” “the obtained parameter set”.

Claim 12 recites the limitations “the markings “, “the maximum distance” “the minimum distance”.

Claim 16 recites the limitations “said mentioned differently sized marking sets”, “the smaller ones of said markings sets” and “the larger marking sets.

Claim 18 recites these limitations “the operating room” and “the patient”.

Art Unit: 3768

Claim 19 recites these limitations “the module”, “the stereoscopic image analysis”
“the stereo camera pair”.

There are insufficient antecedent basis for these limitations in the claims.

8. Regarding Claims 26 and 27, the phrase "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 26, 27 and 33 recite these limitations “the center of the image”,

Claim 28 recites the limitation “the projection of markings”, “the areas of the field of operation marked”

There are insufficient antecedent basis for these limitations in the claims.

Claim 29, line 3 recites "it." This limitation renders the claim indefinite because one cannot be certain what "it" is intended to refer to

Claim 30 recites the limitation “the image of situs”

Claim 31 recites the limitation “the currently obtained topographic data”, “the same” and “the correction”.

Claim 34 recites the limitation “the projection of visible light”.

Claim 35 recites the limitation “the cameras”, “the device”

There are insufficient antecedent basis for these limitations in the claims.

9. **NOTE:** The claims and specification are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with errors (see above rejections).

Art Unit: 3768

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the claims and specification. ***No new matter should be entered.***

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-35 are rejected under 35 U.S.C. **102(b)** as being anticipated by **Mizoguchi et al (US Pub. 2002/0151784)**.

12. Re Claim 1: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation, especially neuronavigation, in surgery with an operating microscope and at least one optoelectronic image receiver, which may also be connectable to a microscope (**See abstract**) , and a computer system, wherein the data obtained (**See Paragraph [0048]**), from the at least one image receiver (**See Paragraph [0042], two CCD cameras**), each of which lie in the microscope field-of-view of the operator (**See fig.1**), contain information about the location of the operating instrument, especially of the tip of this instrument (**See Paragraph [0056]**), wherein the actual position of the instrument in the x- and y-direction as well as in the z-direction of a three-dimensional coordinate system is continuously or intermittently determined from the respective location data and wherein especially for the positional determination in the z-direction a distance determination is

Art Unit: 3768

carried out by means of a depth of focus evaluation (**See Paragraph [0100]**) , and/or a stereoscopic image analysis (**See Paragraph [0035],[0077]**).

13. Re Claims 2 and 3: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein the optoelectronic image receiver(s) is/are directly coupled to the observation beam path, especially by means of beam splitters (See Paragraph [0042], two CCD cameras) and wherein at least one separate image receiver beam path not depending on the observation beam path is provided, which is directed to the microscope field-of-view of the operator (**See Fig.1**).

14. Re Claims 4 and 9: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein the location of the operating microscope in space is detected and said operating microscope positional data are supplied to the computer system (**measuring unit and workstation**) so as to transform the positional data of the instrument into a higher ranking space coordinate system by including existing data on the current position of the patient and preoperatively obtained three-dimensional data from the interior of the patient (**See Paragraph [0042] and [0047]**).

15. Re Claim 5: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein beside the data acquisition for the intraoperative location and position determination of a navigational instrument by means of known optical and/or magnetic methods, a supplementary three-dimensional position detection is carried out by means of the data provided by the image receiver of the operating microscope (**See Paragraph [0047]**).

Art Unit: 3768

16. Re Claims 6-8, 20, 21 and 24-35: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein for the detection of the location of the operating microscope in space, a stereo camera pair is provided at or on the microscope, which allows a motion tracking relative to fixed **markings** provided to the patient and/or in space **(See Paragraphs [0044] and [0077])**.

17. Re Claims 10-19: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein the operating microscope comprises two optical channels brought out of center behind a common front lens having a common object plane and the same magnification for both optical channels, wherein a correction function for the distortion errors is incorporated in the stereoscopic image analysis, which is dependent on the currently used settings of zoom and focus **(See Fig. 3 and [0100])**.

18. Re Claims 22 and 23: **Mizoguchi et al** teach a method for the optimization of identification of the current position in navigation wherein the module comprises one or more receivers of a time of flight distance measurement system based on sound or ultrasound which operates in the time or frequency domain **(See Paragraphs [0038], [0041], [0047])**.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3768

20. Evans et al (Patent 5,792,147), Guthrie et al (Patent 5,971,997), Shioda et al (Patent 6,661,571), Lipow (Pub 2004/0243147) and Kockro (Pub. 2004/0254454) teach related invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAWRENCE N. LARYEA whose telephone number is (571)272-9060. The examiner can normally be reached on 9:30 a.m.-5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

LNL

/Eric F Winakur/
Primary Examiner, Art Unit 3768